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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Maes, et al.

Serial No.: 09/773,351

Group Art Unit: 1617

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Examiner: Jiang, Shaojia A.

PATENT

For: Cholesterol Sulfate and Amino Sugar Compositions for Enhancement of Stratum Corneum Function

RESPONSE PURSUANT TO 37 CFR 1.114

AMENDMENTS

1 (currently amended): A composition for topical application to the skin comprising a mixture of effective

amounts of cholesterol sulfate or salts thereof, and integral with an exfoliant added to in a cosmetically or

pharmaceutically acceptable vehicle.

2 (original): The composition of claim 1 wherein the cholesterol sulfate or salts thereof is present in an

amount between about 0.05 to about 5.00 percent, and the exfoliant is present in an amount between 0.1 to

about 10.0 percent.

3 (original): The composition of claim 1 wherein the composition contains a salt of cholesterol sulfate.

4 (original): The composition of claim 3 wherein the salt is potassium.

5 (original): The composition of claim 1 wherein the exfoliant is an amino sugar selected from the group

consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof.

6 (original): The composition of claim 1 further comprising at least one fatty acid selected from the group

consisting of butyric acid, caproic acid, octanoic acid, decanoic acid, dodecanoic acid, tetradecanoic acid,

palmitic acid, stearic acid, linoleic acid and oleic acid.

7 (original): The composition of claim 6 wherein said fatty acid is linoleic acid.

8 (original): The composition of claim 1 further comprising cholesterol.

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9 (original): The composition of claim 1 further comprising both linoleic acid and cholesterol.

10 (original): The composition of claim 1 further comprising sclareolide.

11 (original): The composition of claim 1 further comprising a protease inhibitor selected from the group consisting of white birch extract, silver birch extract, *Boswellia* extract, bearberry extract, *Centella asiatica* extract, and *Pygeum africanum* extract.

12 (previously presented): The composition of claim 1 further comprising both sclareolide and white birch extract.

13 (currently amended): A cosmetic or pharmaceutical formulation for topical application of a composition to the skin, the formulation containing a mixture comprising cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and from about 0.1 to about 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition added to being integral with one another in a cosmetically or pharmaceutically acceptable vehicle.

14 (original): The formulation of claim 13 further comprising both cholesterol and a fatty acid selected from the group consisting of butyric acid, caproic acid, octanoic acid, decanoic acid, dodecanoic acid, tetradecanoic acid, palmitic acid, stearic acid, linoleic acid and oleic acid.

15 (original): The formulation of claim 14 wherein the fatty acid is linoleic acid present in an amount less than 1 percent and the cholesterol is present in an amount less than 1 percent.

16 (currently amended): A method for improving or maintaining a healthy skin barrier which comprises adding an effective amount of a <u>an integral mixture</u> to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent by weight of the composition, and from about 0.1 to 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof, and applying said mixture to the skin.

17 (original): The method of claim 16 in which the mixture comprises from about 0.1 to about 2.0 percent cholesterol sulfate.

18 (previously presented): The method of claim 16 in which the composition comprises about 0.04 to about 1.0 percent cholesterol sulfate.

19 (currently a mended): A method of treating or reducing damage to the skin, wherein the damage is associated with a reduction or loss of skin barrier function, which comprises adding an effective amount of a an integral mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and about 0.1 to about 10.0 percent of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition, and applying said mixture to the skin.

20 (previously presented): The method of claim 19 further comprising cholesterol sulfate or salts thereof in an amount of about 0.1 to 2.0 percent, about 0.5 to 8.0 percent of N-acetyl-D-glucosamine, cholesterol in an amount of about 0.2 to 1.0 percent, linoleic acid in an amount of about 0.2 to 1.0 percent by weight of the composition, sclareolide in an amount of about 0.001 to about 1.000 percent, and white birch extract in an amount of about 0.001 to about 1.000 percent.